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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. FSIS-2012-0038]

Changes to Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing Escherichia coli and Salmonella

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to comments on an August 28, 2013, Federal Register document, "Changes to Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing Escherichia coli and Salmonella" and announcing its plans to begin analyzing for Salmonella all beef product it analyzes for Shiga toxin-producing Escherichia coli (STEC). After reviewing the comments received on the August 2013 document, FSIS is affirming the plans for addressing Salmonella in raw beef products that it announced in that document and will proceed with implementing those plans.

DATES: On June 29, 2014, FSIS will discontinue Salmonella sampling set procedures ("HC01") in ground beef products, except

in establishments with results that exceeded the standard for Salmonella in that establishment's most recently completed set (i.e., in those establishments in Category 3). At the same time, FSIS will begin analyzing for Salmonella all raw beef samples it collects for STEC analysis and will increase the raw ground beef sample portion for Salmonella analysis from 25 grams to 325 grams.

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SUPPLEMENTARY INFORMATION:

Background

On August 28, 2013, FSIS published in the Federal Register a document announcing changes that it intended to make in its Salmonella sampling program for raw beef products (78 FR 53017). The Agency requested comment on these changes, with the aim of assessing whether it should alter any of its plans on the basis of the information or data it received.

FSIS announced that it would begin analyzing for Salmonella all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that it collects for STEC testing, including raw ground beef products FSIS samples at retail stores and ground beef, trim, and other

raw ground beef components FSIS samples at import establishments. FSIS also explained that when it begins analyzing for Salmonella the product collected for STEC analysis, the Agency will also begin analyzing for Salmonella the follow-up samples it collects in response to STEC positive results. FSIS further explained that it is not making any changes to the STEC sampling and testing programs at this time.

FSIS announced that, once the "co-analysis" begins, it would increase the raw ground beef sample portion for Salmonella analysis from 25 grams to 325 grams. FSIS explained that to support an increase in the sample size analyzed, FSIS evaluated the FSIS Salmonella detection method (FSIS Microbiology Laboratory Guidebook Chapter 4.06) using 325 gram samples. Based on this analysis, FSIS expects the increase in the analytical portion size to have at least the same, but likely more of a positive, impact on public health because the likelihood of detecting positive samples increases with the analytical portion size.

FSIS described how it intends to use results generated from its raw ground beef (MT43) and beef manufacturing trimming (MT60) verification sampling programs to estimate the Salmonella prevalence in those products and to develop a new Salmonella performance standard for ground beef product. FSIS explained

that the low incidence of Salmonella on beef manufacturing trimmings does not support development of a Salmonella performance standard for those trimmings. FSIS also explained that, because of the limited number of available samples scheduled and collected, the Agency does not believe it is possible to estimate prevalence for Salmonella in raw ground beef components other than beef manufacturing trimmings (such as bench trim).

FSIS explained that it intends to develop a new performance standard that will likely lead establishments producing ground beef to strengthen their own Salmonella control measures. Such changes at establishments will likely have a positive impact on public health.

FSIS also announced that it intends to enumerate samples that confirm Salmonella-positive using the Most Probable Number (MPN) quantitative procedure, and that it will continue to evaluate Salmonella isolates from the screen-positive samples for multi-drug resistance, to serotype the samples, and to use pulsed-field gel electrophoresis (PFGE) to identify specific strains of Salmonella. FSIS explained that, through this analysis, FSIS will determine whether Agency-positive Salmonella results are associated with illnesses or serotypes of human health significance. If FSIS finds that establishments have

produced product associated with illness, FSIS will typically conduct an Incident Investigation Team Review or Food Safety Assessment at the establishment.

FSIS also announced in the same document that, except for establishments with results that exceeded the standard for Salmonella in that establishment's most recently completed set (i.e., those establishments in category 3), it would discontinue Salmonella sampling sets for ground beef products at least until it establishes a revised Salmonella performance standard for ground beef. FSIS explained that, when collecting samples for a Salmonella set, FSIS inspection program personnel submit the samples to FSIS laboratories for analysis over a defined number of sequential days of production to complete the sample set.

FSIS stated that it would consider alternatives to set-based testing for Salmonella, including a "moving window" approach to process control, to be put into effect when the revised performance standard is implemented. FSIS explained that under a "moving window" approach, the Agency would evaluate a certain number of sequential results from a single establishment to assess process control. For example, if the Agency chose to evaluate 20 results under the "moving window" approach, it would assess the most recent 20 FSIS results for a particular establishment. FSIS explained that this new approach would allow

for on-going scheduled Salmonella sampling, similar to the approach FSIS uses for STEC testing, and would provide FSIS with more flexibility for scheduling sample collection at different establishments. The Agency requested comment on the "moving window" approach.

In addition, FSIS explained that it is considering implementing new sampling of product classes not subject to the Agency's sampling and testing for Salmonella. The Agency stated that it was considering sampling and testing for Salmonella in pork trim, pork parts, ground pork, chicken parts, and lamb carcasses.

FSIS explained that the changes that it announced to its Salmonella sampling procedures would permit it to analyze more samples at the same time at lower cost to the Agency than does the current method. Through this new approach, FSIS will be able to analyze for Salmonella beef manufacturing trimmings and other raw ground beef components at slaughter establishments. Sampling these products will provide FSIS more information about Salmonella at these establishments than FSIS was able to gather through carcass testing.

The final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems," which FSIS published

on July 25, 1996 (61 FR 38805–38989; *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf)*, set Salmonella performance standards for establishments producing selected classes of raw meat products, including ground beef, steers and heifers, and cows and bulls (9 CFR 310.25(b)). In 2011, FSIS stopped sampling and testing for Salmonella in steers and heifers and cows and bulls because percent positive findings were very low (less than one percent), and this carcass sampling was expensive for the Agency.

After carefully considering all comments received, FSIS has determined that no changes are needed in the plans it announced in the August 2013 Federal Register document. Thus, on June 29, 2014, FSIS will discontinue Salmonella sampling set procedures in ground beef products ("HC01"), except in those establishments in Category 3. At the same time, FSIS will begin analyzing for Salmonella all raw beef samples it collects for STEC analysis and will increase the raw ground beef sample portion for Salmonella analysis from 25 grams to 325 grams.

Also, consistent with what the Agency announced in the August 2013 Federal Register document, FSIS intends to use the results from its verification sampling program to estimate Salmonella prevalence in raw ground beef and beef manufacturing trimmings and to develop a new Salmonella performance standard

for ground beef product. FSIS will announce any new standard in the Federal Register and request comment on it before implementing it. FSIS intends to develop and propose the new standard next fiscal year.

In addition, FSIS announced its Salmonella Action Plan on December 4, 2013.[1] According to the plan, FSIS intends to complete a risk assessment and develop Salmonella performance standards for comminuted poultry and poultry parts this fiscal year and performance standards and, if needed, sampling programs for hog carcasses and pork products next fiscal year.

The following is a summary of the relevant comments received and FSIS's responses.

Summary of Comments and Responses

FSIS received ten comments in response to the August 2013 Federal Register document. The comments were from trade associations, private citizens, consumer advocacy associations, including a joint submission from two consumer advocacy organizations, a large meat processor, and a foreign government.

A. General Support for the Proposed Changes

Comments: Most of the comments supported the proposed changes to procedures for Salmonella verification sampling and

1 http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella/sap.

testing of raw beef products because the changes will improve Agency efficiencies. In addition, several comments supported the Agency's intent to estimate Salmonella prevalence in raw beef products, to serotype or enumerate positive samples, to identify specific strains of Salmonella, and to develop a new Salmonella performance standard for ground beef.

B. General Opposition to Verification Sampling and Testing of Raw Beef Products

Comment: One private citizen opposed FSIS verification sampling and testing for Salmonella in raw beef products because of recent research suggesting that Salmonella may naturally occur in the lymph nodes of cattle. According to the commenter, this detail makes it impossible for establishments to completely eliminate Salmonella from any raw beef product. The commenter recommended that, rather than focusing on verification sampling at the establishment, FSIS focus its resources on researching pre-harvest controls for Salmonella in cattle and educating consumers on how to properly handle and cook raw beef products.

Response: FSIS collects samples of meat and poultry products from an establishment for pathogen testing to verify whether the establishment is effectively addressing the pathogen. When FSIS collects product for Salmonella analysis as part of a set, FSIS verifies whether the establishment is

maintaining process control in slaughter or certain processing operations. FSIS uses the results of these and other verification tasks to guide policy development and focus Agency resources on those activities that will best protect public health.

In May 2010, FSIS issued guidance to beef slaughter establishments on pre-harvest management controls for reducing Escherichia coli (E. coli) O157:H7 shedding in beef cattle.[2] FSIS is updating this guidance to include other STEC and intends to make the updated guidance available to the establishments soon. Similarly, in November 2011, FSIS met with stakeholders to discuss pre-harvest pathogen control strategies for reducing prevalence of STEC and of Salmonella in and on cattle (76 FR 63901; Oct. 14, 2011). In addition, FSIS conducts multiple consumer education campaigns to inform the American public of the proper methods for handling and cooking meat and poultry, so that any potential food-safety hazard is reduced to a minimum.[3]

Comment: A large meat processor generally opposed FSIS verification sampling and testing of portioned fine and coarse ground beef products that are ground at a primary establishment

2 Available at http://www.fsis.usda.gov/wps/wcm/connect/d5314cc7-1ef7-4586-bca2-f2ed86d9532f/Reducing_Ecoli_Shedding_In_Cattle_0510.pdf?MOD=AJPERES.

3 See http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education.

and subsequently portioned at a second establishment because sampling and testing of product from the second establishment is potentially duplicative.

Response: FSIS collects samples of ground product at establishments that grind product or form patties. FSIS does not collect samples of ground beef products for E. coli O157:H7 (or other STEC) analysis at establishments that only pack or portion and do not grind or form patties. When FSIS begins analyzing all raw beef samples collected for STEC analysis for Salmonella, FSIS would also analyze any raw ground beef product samples (e.g., formed raw beef patties) collected for E. coli O157:H7 for Salmonella.

C. Larger Analytical Sample Portion

Comment: Two trade associations requested additional information on the protocol for obtaining the larger 325-gram analytical portion used for Salmonella testing.

Response: FSIS inspection program personnel will continue to collect samples of raw beef products for FSIS verification testing using the collection protocols outlined in FSIS Directive 10,010.1[4] and associated FSIS Notices. FSIS has determined that the amount of product inspectors currently collect (about 2 lb or 907 g) will provide the FSIS laboratories

4 Available at http://www.fsis.usda.gov/wps/wcm/connect/c100dd64-e2e7-408a-8b27-ebb378959071/10010.1Rev3.pdf?MOD=AJPERES.

with sufficient product to analyze the samples using the larger analytical portion (325 g) for both Salmonella and STEC.

Comment: A trade association and a large meat processor requested that the Agency consider and make note of the larger portion for Salmonella analysis when reporting program results because the larger analytical portion will likely yield more positive results.

Response: When FSIS begins posting on its Web page the results obtained using the larger analytical portion, FSIS will note that the results are from samples it analyzed using the larger portion size. In addition, the Agency will report periodically to each establishment whose product the Agency collects the establishment's test results compared with industry-wide results. FSIS will also post aggregate results of this testing as part of its quarterly report on Salmonella.

Comment: Another trade association suggested that FSIS evaluate whether increasing the analytical portion from 25 to 325 grams increases the likelihood of detecting Salmonella positive samples.

Response: As noted above, based on the analysis discussed in the 2013 Federal Register document, FSIS expects the increase in the analytical portion size to have at least the same, but likely more of a positive impact on public health because the

likelihood of detecting positive samples increases with the analytical portion size.

Comment: One trade association noted that many of its members supply raw beef products to the Agricultural Marketing Service (AMS) for various Federal food and nutrition assistance programs. The association asked FSIS to coordinate with AMS on related sampling protocol requirements to ensure a seamless transition.

Response: FSIS has notified AMS of its intent to make changes in its Salmonella verification sampling program for raw beef products.

D. Estimating Prevalence

Comment: The consumer group joint submission stated that FSIS failed to address two critical statistical requirements when estimating prevalence of Salmonella in ground beef: the sampling must be representative of population and the sampling must provide desired precision.

Response: The statistical sampling design for FSIS's raw ground beef verification sampling program is detailed in the Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs (FSIS, 2011).[5] The sampling design is volume-weighted (i.e., probability is

5 Available at http://www.fsis.usda.gov/wps/wcm/connect/0816b926-c7ee-4c24-9222-34ac674ec047/FSIS_Sampling_Programs_Report.pdf?MOD=AJPERES.

proportional to sample size) to provide for sampling that is representative of national production volume.

In 2012, FSIS determined that its MT43 sampling program is sufficiently representative and provides the needed precision to compute prevalence of E. coli O157:H7 in raw ground beef.[6] Moreover, FSIS expects that Salmonella will occur in raw beef products at a rate higher than that for E. coli in raw ground beef. For these reasons, FSIS's ground beef verification sampling program will adequately support the development of an estimate of the prevalence of Salmonella in raw beef products.

E. Risk Assessment

Comment: A trade association requested that FSIS also conduct a risk assessment that addresses the risk that Salmonella presents in pork, chicken, turkey, and ready-to-eat products.

Response: As previously stated, FSIS intends to complete a risk assessment for Salmonella in comminuted poultry and poultry parts this fiscal year. FSIS will develop additional risk assessments concerning Salmonella and other products as necessary, for example, should FSIS decide to evaluate whether to propose performance standards for additional products.

6 Available at http://www.fsis.usda.gov/wps/wcm/connect/56b2ccbd-ad57-4311-b6df-289822d28115/Prevalence_Estimates_Report.pdf?MOD=AJPERES.

F. Development of a Salmonella Performance Standard

Comment: Because beef products have the greatest seasonal variation among the products subject to FSIS verification sampling and testing, several industry trade associations and a large meat processor asked that FSIS ensure it has data from at least a 12-month period before conducting the risk assessment and developing a performance standard.

Response: As the new ground beef data are collected, FSIS will evaluate the suitability of those data for use in performance standard development. It should be noted, however, that the current ground beef performance standard was developed using approximately 7 months of data.[7]

G. "Moving Window" Approach

Comment: Several comments requested a more detailed explanation of how the "moving window" approach will work. More specifically, the joint submission requested additional information on how big the window would be, how often the Agency would sample product at a single establishment, and the Agency's analytical capacity to adequately take such an approach. An industry trade association requested that FSIS develop a written protocol for this approach and make the protocol available for

7 Available at http://www.fsis.usda.gov/wps/wcm/connect/317ae862-1980-4c87-9bea-85bf4491b420/rwgrbeef.pdf?MOD=AJPERES.

review and comment prior to implementation.

Response: As explained in the August 2013 Federal Register document, FSIS intends to take a "moving window" approach when scheduling sampling and evaluating results generated by its Salmonella verification testing program for ground beef products under a new performance standard. With a "moving window" approach, FSIS will evaluate a predetermined number of sequential results for ground beef product from a single establishment to assess process control. The size of the moving window and the threshold for positives within that window will be included in the performance standard developed. At the same time it announces the new performance standard for raw ground beef, FSIS will detail its plans for the new approach in the Federal Register and consider any comments received on it prior to implementation. FSIS is considering using this approach for all Salmonella performance standards and will provide more explanation of how the approach will work for all classes of product

Comment: Several trade associations requested clarification on how the Agency will respond with follow-up sampling in the event of a positive Salmonella result when the sample is negative for STEC.

Response: As FSIS explained in the 2013 Federal Register

document, because FSIS does not typically consider Salmonella an adulterant in raw beef, when FSIS begins analyzing samples collected for STEC analysis for Salmonella, FSIS will not routinely conduct follow-up sampling in response to a single positive Salmonella result. However, if FSIS Salmonella testing data from an establishment show a high number of positives, high levels of Salmonella for each positive, or serotypes of human health significance, FSIS may perform follow-up testing or conduct a for-cause Food Safety Assessment that includes follow-up testing or take other appropriate actions, such as additional sanitary dressing verification procedures, at the establishment that produced the product.

H. Import Inspection

Comment: A foreign government requested clarification on regulatory control actions the Agency will take when raw beef product imported into the United States is sampled by FSIS at the port of entry and tests positive for Salmonella.

Response: As stated above, Salmonella is not an adulterant in raw meat products. Therefore, a positive test result for Salmonella in imported raw beef product sampled by FSIS import inspection personnel would not result in regulatory control actions at port-of-entry.

FSIS does not collect imported raw products for Salmonella analysis. FSIS stated that it intended to begin testing for Salmonella imported raw beef products it samples for STEC in the August 2013 Federal Register document. On June 29, 2014, FSIS will begin analyzing for Salmonella all imported raw beef samples it collects for STEC analysis. FSIS will post aggregate results of this testing on the FSIS Web site as part of its quarterly report on Salmonella. In addition, FSIS will use enumeration and serotype data of this testing to identify trends within the sampling data, to determine whether an isolate has a historical association with human illness, and to identify clusters of patterns.

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Done at Washington, DC on: June 2, 2014.

Alfred V. Almanza,

Administrator.

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